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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,526	10/01/2003	Patrick H. Roseboom	960296.98687	8345

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EXAMINER	
KATCHEVES, KONSTANTINA T	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,526	ROSEBOOM ET AL.	
	Examiner	Art Unit	
	Konstantina Katcheves	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are pending in the present application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7, 11, 17 and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 16, 21 and 23 of copending Application No. 10/293702. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims

are generic to all that is recited in the claims Application No. 10/293792. That is, the claims of Application No. 10 10/293792 fall entirely within the scope of the instant claims or, in other words, the instant claims are anticipated by the claims of Application No. 10/293792. Specifically, the claims of the copending application are drawn to nucleotide sequences comprising nucleotides 1-4917 of SEQ ID NO:1, like the instant claims, constructs and host cells comprising said nucleotides and methods.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the

invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The present invention is drawn to fragments and complement of nucleotides 1-4917, nucleotides 4868-4917 and nucleotides 4827-4917 of SEQ ID NO:1, nucleic acid constructs and host cells comprising said fragments, and methods of identifying and using said fragments. SEQ ID NO:1 represents the human corticotrophin releasing factor binding protein gene. The present claims are drawn to undefined yet functional "fragments," or "complements" of the claimed sequences.

The instant claims are drawn to sequences with undefined modifications, which have certain activities or functions. For example, in claim 19 this activity is a promoter activity. These are genus claims that encompass a wide array of molecules. The specification does not disclose all of the functional fragments or complements embraced by the breadth of the claims. The specification also fails to provide any teachings as to how the structures of these sequences relate to their function, *e.g.* promoter function. The specification does not describe the complete structure of a representative number of species. Absent such teachings and guidance as to the structure-function relationship of these molecules, the specification does not describe the claimed sequences in such full, clear, concise and exact terms so as to indicate that Applicant had possession of these

molecules at the time of filing of the present application. Thus, the written description requirement has not been satisfied.

Claims 1-6 and 8-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Nature of the invention and breadth of the claims

The present invention is drawn to fragments and complement of nucleotides 1-4917, nucleotides 4868-4917 and nucleotides 4827-4917 of SEQ ID NO:1, nucleic acid constructs and host cells comprising said fragments, and methods of identifying and using said fragments. SEQ ID NO:1 represents the human corticotrophin releasing factor binding protein gene. The present claims are drawn to undefined yet functional "fragments," or "complements" of the claimed sequences.

Guidance provide and presence of working examples in the specification

The specification does not disclose any of the functional fragments or complements of the sequences of SEQ ID NO:1 embraced by the claims. Moreover, the specification fails to disclose any teachings as to how the structures of these sequences relate to their function. In other words, the specification fails to disclose what sequence or domains of SEQ ID NO:1 or SEQ ID NO:2 are required for a part, portion or fragment to maintain the claimed activities.

State of the prior art and unpredictability of the art

Although the state of the art is high, it would be unpredictable to make parts or fragments of the presently claimed nucleic acid sequences, which are functional. At best, one of skill in the art may be able to screen for certain structural characteristics or function. Screening would not eliminate the unpredictability of false positive or negative results. For instance, one of skill in the art may make a construct comprising a part of SEQ ID NO:1, yet the fragment may have no activity or may have activity at such a basal level that the screens used by one of skill in the art would not be adequate to identify the construct. Also with regard to the method of screen for fragment activity in claim 7, the

claim reads on "(a) providing a nucleic acid that comprises the fragment and a heterologous reporter gene operably linked to the fragment." Moreover, screening does not enable one of skill in the art to make or use the claimed vectors with the desired activity for each component *de novo*. It is merely a method of finding not of making. Thus, given the nature of the invention, the scope of the claims, the lack of guidance in the specification and the unpredictability of the art, it would require undue experimentation for one of skill in the art to make and use the invention claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is inherently vague and indefinite because it states: "a fragment of the 4917 bp upstream of the TSP of human CRF-BP gene (nucleotides 1-4917 of SEQ ID NO:1)." First, it is unclear what the fragment of this claim is. Is this the fragment as claimed in the nucleotides recited in claims 1-3 and the construct recited in claim 4? Alternatively, does this fragment comprise nucleotides 1-4917 of SEQ ID NO:1?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number S60697 1993.

The present claims are drawn to fragments or complements of nucleotides 1-4917, nucleotides 4868-4917 and nucleotides 4827-4917 of SEQ ID NO:1.

Accession number S60697 discloses a fragment having 100 per cent identity to nucleotides 4868-4917 of SEQ ID NO:1. Accession number S60697 discloses that the fragment is a corticotrophin releasing factor binding protein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accesion number S60697 as applied to claims 1-3 above, and further in view of Cortright et al. (Endocrinology Vol.138 no.5 2098-2108 (1997)).

Accession number S60697 discloses a fragment having 100 per cent identity to nucleotides 4868-4917 of SEQ ID NO:1. Accession number S60697 discloses that the fragment is a human corticotrophin releasing factor binding protein. Reporter constructs and transfected cells have not been taught.

Cortright et al. teach a CRH-BP-reporter construct. These constructs are transfected into host cells for expression. See abstract and introduction, paragraph 2. Cortright et al. fail to teach the sequence above, *i.e.* human corticotrophin releasing factor binding protein.

It would have been obvious to one of skill in the art at the time the invention was made to use the human CRH-BP sequence of SEQ ID NO:1 to make a reporter construct comprising said sequence and transfecting host cells with said construct. Although Cortright et al. do not teach human CRH-BP-reporter constructs, they do teach rat CRH-BP-reporter construct for transfection into cells. One of ordinary skill in the art would have been motivated to make the construct comprising the human CRH-BP and reporter gene to measure promoter activity as is done by Cortright et al. See abstract and introduction, paragraph 2. The making of heterologous gene-reporter constructs and transfection of genes expressing said constructs is germane to the art such that the ordinary skilled artisan would reasonably expect the success of such a construct in expressing the reporter to measure activity. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
Examiner
Art Unit 1636